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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/320,100 05/26/99 ANSALDI

D P1363R1

HM12/1012

EXAMINER

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SOUTH SAN FRANCISCO CA 94080

HUNT, J

ART UNIT	PAPER NUMBER
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1642

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DATE MAILED: 10/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. 09/320,100	Applicant(s) Ansaldi et al.
Examiner Jennifer Nichols, Nee Hunt	Group Art Unit 1642

Responsive to communication(s) filed on Jul 31, 2000.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 1-13 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-13 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 9

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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***Response to Amendment***

Claims 1-13 are pending in the application.

***Claim Rejections Withdrawn***

1. The rejection of claims 1-13 under 35 U.S.C. 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention is withdrawn in light of applicant's arguments and the amendments thereto.
2. The grounds of rejection of claims 1, 5, 7, 9, and 11-13 under U.S.C. 102(b) as being anticipated by D'Andrea et al. Is withdrawn in light of the amendments thereto.

***Claim Rejections Maintained***

3. The grounds of rejection of claims 1-2, 5-7, and 9-13 under U.S.C. 102(b) as being anticipated by Yang et al., Journal of Chromatography, A743, 1996 is maintained for reasons of record.

Applicant argues that Yang et al. Is not trying to separated monomers from dimers, but rather is separating monomers from monomers. Applicant cites as support that Yang teaches that IgG's are often differentially glycosylated or post-translationally different. Applicant further cites that the figures "do not represent separation of monomers". Applicant's arguments filed 7-31-2000 have been fully considered but they are not persuasive.

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The method of Yang et al. Is identical to the claimed method. As set forth in the previous office action, Yang et al. teaches a method of applying a mixture (which includes IgG's, ascites and sera, see abstract and examples 3.6.1 and 3.6.2) to a cation exchange chromatography resin with numerous pH's in the 6-7 range or a anion exchange resin with numerous pH's in the 6-9 range.(pages 173-177) Therefor Yang et al. does separate monomers from a mixture of dimers and multimers (serum and ascites). Furthermore, Yang et al. teaches purification of immunoglobulins using an identical method to that instantly claimed, and thus "purification" would include elution of the IgG monomers from a mixture (serum or ascites) which contains monomers and dimers or multimers. With regard to the new limitation that the separated monomer has a purity of greater than 99.5% and the monomer yield is greater than 90%, since the method steps of Yang et al. are identical to the instant method steps, absent evidence to the contrary, one of skill in the art would conclude that the method of Yang yielded comparable results.

4. The grounds of rejection of claims 1-2, 5-7, and 9-13 under U.S.C. 102(b) as being anticipated by Hahn et al., Chromatography, 795, pages 277-287 (1998) is maintained for reasons of record.

Applicant argues that Hahn et al. teaches separation of different proteins but not monomers and dimers. Applicant's arguments filed 7-31-2000 have been fully considered but they are not persuasive.

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Applicant provides no evidence to support the assertion that the mixture taught in Hahn et al. does not contain dimers and/or multimers. Furthermore, Hahn et al. teaches purification of immunoglobulins using an identical method to that instantly claimed, and thus "purification" would include elution of the IgG monomers from a mixture (bovine whey) which contains monomers and dimers or multimers. With regard to the new limitation that the separated monomer has a purity of greater than 99.5% and the monomer yield is greater than 90%, since the method steps of Hahn et al. are identical to the instant method steps, absent evidence to the contrary, one of skill in the art would conclude that the method of Hahn yielded comparable results.

5. The grounds of rejection of claims 1-2 and 4-13 under 35 U.S.C. 103(a) as being unpatentable over Yang et al., in view of US Patent 4,764,279, Tayot et al is maintained for reasons of record.

Applicant argues that Tayot fails to overcome the deficiencies of Yang et al. and fails to teach separation of a monomer from a mixture of monomers and dimers. Applicant's arguments filed 7-31-2000 have been fully considered but they are not persuasive.

Applicant's arguments regarding Yang et al. have been addressed supra. With regard to applicant's argument that the mixture in Tayot does not contain monomers, the mixture is blood and thus would contain dimers and multimers inherently.

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6. The grounds of rejection of claims 1-3 and 5-13 under 35 U.S.C. 103(a) as being unpatentable over Yang et al and Hahn et al., in view of Oncogene Science catalog 1992, pages 18 and 35 is maintained for reasons of record.

Applicant argues that Oncogene Science fails to overcome the deficiencies of Yang et al. and Hahn et al, and fails to teach separation of a monomer from a mixture of monomers and dimers. Applicant's arguments filed 7-31-2000 have been fully considered but they are not persuasive.

Applicant's arguments regarding Yang et al., and Hahn et al have been addressed supra. With regard to applicant's argument that the mixture in Oncogene Science does not contain monomers, the reference is submitted to set forth the desirability of purification of the specific antibodies of claim 3. It is not necessary that the claimed invention be expressly suggested by in any one or all of the references to justify combining their teachings; rather the test is what the combined teachings of the references would have suggested to one of ordinary skill in the art. (*In re Keller*, 642 F.2d 413,288 USPQ 871 9ccpa 1981)

No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Nichols, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [\[anthony.caputa@uspto.gov\]](mailto:[anthony.caputa@uspto.gov]).

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly

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signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Nichols, Nee Hunt

October 10, 2000



ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
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